# 105 CMR 721.000: STANDARDS FOR PRESCRIPTION FORMAT AND SECURITY IN MASSACHUSETTS

**Bold blue = new language**
~~Red-strikethrough =~~ deleted language
Regular text = existing language

Section



## 721.001: Purpose

The purpose of 105 CMR 721.000 is to specify the requirements for prescription format and security in Massachusetts.

## 721.003: Scope and Application

105 CMR 721.000 establishes the standards for format and security in the Commonwealth that all prescriptions issued by practitioners or reduced to writing by pharmacists must meet in order to comply with M.G.L. c. 112, § 12D and c. 94C.

## 721.010: Definitions

The terms used in 105 CMR 721.000 shall have the meanings set forth in 105 CMR 721.010. Terms defined in M.G.L. c. 112, § 12D and c. 94C, § 1, **and 105 CMR 700.001,** and not defined in 105 CMR 721.010 shall have the meanings set forth therein when used in 105 CMR 721.000, unless the context clearly requires a different interpretation.

Authentication means that the identities of the parties sending and receiving electronic prescription data are duly verified.

**Compounded Drug Preparation means a preparation created through mixing, assembling, altering, packaging, and labeling of a controlled substance as the result of a practitioner's order or in anticipation of such an order based on routine, regularly observed prescribing patterns. A compounded drug preparation shall not include the reconstitution of commercially available controlled substances.**

Comment [A1]: Defined as term is now used in this regulation.

Confidentiality means that only authorized persons have access to prescription data.

Content Integrity means that the electronic prescription data have not been altered or compromised in transmission.

Drug Product means the final dosage form of a drug that is marketed under a brand or generic name.

**Electronic Prescribing System means an electronic prescribing system that meets federal requirements for electronic prescriptions for controlled substances, including the**

validation and authentication requirements pursuant to 21 CFR 1311 Subpart C for generation of electronic prescriptions for controlled substances. Electronic prescribing systems may be stand-alone systems, where the sole purpose for the system is the generation and transmission of electronic prescriptions, or part of a more comprehensive healthcare system such as an electronic health record.

**Electronic Prescription** means a prescription which is generated on an electronic prescribing system and sent by electronic transmission to a pharmacy without alteration of the prescription information. As used in 105 CMR 721.000, the term electronic prescription does not include orders for medication that are administered in an inpatient setting.

Comment [A2]: Definition added to implement chapter 208 of the acts of 2018. Definition conforms with statutory definition through reference to other defined terms in this section.

Electronic Signature means an electronic sound, symbol or process attached to or logically associated with a prescription record and executed or adopted by a practitioner with the intent to sign said prescription record and which is validated and authenticated in accordance with M.G.L. c. 110G and 21 CFR 1311 Subpart C and other federal regulations applicable to electronic signatures generated through electronic prescribing systems.

Comment [A3]: Definition amended to conform with new electronic prescribing requirements

**Electronic Transmission** means that the record is seamlessly generated, transmitted and received on systems which are validated and authenticated in accordance with 21 CFR 1311 Subpart C and other federal regulations applicable to electronic transmission of prescriptions. The use of third party intermediaries acting as conduits to route the prescriptions from a prescriber to a pharmacy, where the systems of such third party intermediary meets the security requirements for electronic transmissions, are authorized under 105 CMR 721.000. Transmission by facsimile is not authorized as electronic transmission.

Comment [A4]: Definition added to implement chapter 208 of the acts of 2018.

**ePrescribing** means generating a prescription on an electronic prescribing system and sending by electronic transmission to a pharmacy without alteration of the prescription information.

Comment [A5]: Term and definition included as common trade term.

**Prescription** means an order for a medication or device which is dispensed to or for an ultimate user. A prescription does not mean an order for medication which is dispensed for immediate administration to the ultimate user.

Comment [A6]: Definition added for clarity.

Registration Number means the registration number assigned to a practitioner by the federal Drug Enforcement Agency authorizing them to ~~write~~ generate prescriptions for controlled substances. Practitioners who do not have a DEA Registration Number, as they prescribe only from Sschedule VI, shall use their Massachusetts Controlled Substance Registration number.

Comment [A7]: Definition amended to conform with new electronic prescribing requirements.

Technical Non-repudiation means that parties to the generation, transmission, receipt or storage of an electronic prescription cannot reasonably deny having participated in said activities.

**Written Prescription** means a lawful order from a practitioner for a drug or device for a specific patient that is communicated directly to a pharmacist in a licensed pharmacy; provided, however, that "written prescription" shall not include an order for medication which is dispensed for immediate administration to the ultimate user by a practitioner, registered nurse or licensed practical nurse. For the purposes of 105 CMR 721.000, "written prescription" includes a prescription issued on a system that meets the requirements of 105 CMR 721.030, when such prescription is authorized by 105 CMR 721.070(A)(9).

Comment [A8]: Added statutory definition, plus language regarding Schedule VI systems.

721.020: Prescription Formats

(A) Every prescription ~~written~~ **generated** in the Commonwealth of Massachusetts must be ~~in~~ a an electronic prescription and include an electronic signature unless it is a prescription issued in accordance with an exception listed in 105 CMR 721.070. ~~format that conforms to the following requirements:~~

Comment [A9]: Language updated to implement CARE Act ePrescribing requirements.

(~~A~~B) aA prescription must **enable** ~~permit~~ the practitioner to instruct the pharmacist to

Comment [A10]: Language updated to reflect practice.

dispense a brand name drug product by indicating "no substitution", provided that:
(1) the indication of "no substitution" is not the default indication;
(2) the prescription indicates that "Interchange is mandated unless the practitioner indicates 'no substitution' in accordance with the law"; and

(3) the indication of "no substitution" is a unique element in the prescription and shall not be satisfied by use of any other element, including the signature~~;~~.

~~(B) if the prescription is paper-based, including but not limited to a prescription that is transmitted via facsimile or similar technology, or reduced to writing by a pharmacist, the prescription must be on a form that contains a signature line for the practitioner's signature on the lower portion of the form. Hospital and clinic prescription forms shall contain a line directly below the signature line for the practitioner to print or type his or her name. Below the signature line, or in the case of hospital and clinic prescription forms, below the line provided for the practitioner to print or type his or her name, there shall be a space in which the practitioner may indicate "no substitution". Below this space shall be printed the words "Interchange is mandated unless the practitioner indicates 'no substitution' in accordance with the law";~~

Comment [A11]: Moved to 721.020(F)(1) and amended to remove unnecessary requirements.

~~(C) If the prescription is transmitted electronically, the practitioner shall generate and transmit the prescription in a format that can be read and stored by a pharmacy in a retrievable and readable form;~~

Comment [A12]: As all electronic prescriptions will be transmitted and received on standard federal systems, this caveat is no longer needed.

(~~B~~C) ~~t~~The name and address of the practitioner shall be clearly indicated on the prescription. A hospital or clinic prescription shall have the name and address of the hospital or clinic clearly indicated on the prescription~~t~~.

(~~C~~D) ~~t~~The prescription shall contain the following information:
(1) the registration number of the practitioner;
(2) date of issuance of the prescription;
(3) name, dosage, and strength per dosage unit of the controlled substance prescribed, and the quantity of dosage units;
(4) name and address of the patient, except in a veterinary prescription or a prescription for expedited partner therapy issued in accordance with 105 CMR 700.003(J), in which case the patient, and the address may be left blank; or in the case of a prescription for naloxone the person taking delivery of the naloxone may be used in place of the name of the patient, and the address may be left blank;
(5) directions for use, including any cautionary statements required;
(6) a statement indicating the number of times to be refilled; and
(7) if the prescription is for an opioid substance in Schedule II, a notation that the patient may fill, upon request, the prescription in an amount less than the recommended full quantity indicated.

~~(F) A prescription must be written on a tamper-resistant form consistent with federal requirements for Medicaid.~~

Comment [A13]: Moved to 721.020(F) as part of paper/oral format requirements.

(~~D~~E) A prescription issued by a **certified** nurse practitioner, psychiatric **clinical** nurse **specialist or certified registered nurse** anesthetist ~~or pharmacist~~ shall also contain the name of the supervising physician.

Comment [A14]: Updated terminology and removed pharmacists, as collaborative drug therapy management pharmacists are no long required to comply with this provision.

**(F) Written prescriptions, where permitted, must also comply with procedures set forth in 105 CMR 721.020(F):**
**(1) Written prescriptions issued in accordance with 105 CMR 721.000, including, but not limited to, a prescription that is transmitted via facsimile or similar technology, or reduced to writing by a pharmacist, must be on a form that contains the practitioner's signature;**
**(2) Written prescriptions issued in accordance with 105 CMR 721.000 must be written on a tamper-resistant form consistent with federal requirements for Medicaid.**

721.030: Security Standards for Prescriptions Issued by Prescribers Registered to Prescribe Schedule VI Controlled Substances Only

Comment [A15]: Amendments maintain Schedule VI prescribing system requirements for written prescriptions permitted for prescribers with Schedule VI only MCSR, pursuant to exception in 721.070(A)(9).

~~(A)~~ A schedule VI prescription issued pursuant to 105 CMR 721.070(A)(9) may be transmitted through a system that meets the following requirements ~~electronically provided that~~:

(A~~1~~) ~~if said prescription is for a controlled substance in Schedules II through V, it is validated and authenticated in accordance with M.G.L. c. 94C and applicable Department of Public Health regulations, if any, and 21 CFR 1311 Subpart C and other applicable federal regulations;~~

~~(2) if~~ said prescription is for a controlled substance in Schedule VI that ~~it~~ is validated and authenticated in accordance with requirements in M.G.L. c. 94C and applicable Department of Public Health regulations for oral prescriptions or by utilizing a system that includes:

(1a) a combination of technical security measures, such as, but not necessarily limited to, those listed in Security Standards for the Protection of Electronic Protected Health Information (HIPAA), 45 CFR Part 164, Subpart C, § 164.312, to ensure a reasonable and appropriate level of:

(a)~~1.~~ practitioner and dispenser authentication;
(b)~~2.~~ technical non-repudiation;
(c)~~3.~~ content integrity; and
(d)~~4.~~ confidentiality.

(2b) an electronic signature that is:

(a)~~1.~~ unique to an identified practitioner;
(b)~~2.~~ originated solely by and under the ultimate control of the practitioner; and
(c)~~3.~~ capable of verification.

(3a) reasonable and appropriate security measures to invalidate a prescription if either the electronic signature or the prescription record to which it is attached or logically associated is altered or compromised; and

(B~~3~~) said prescription meets any other generally applicable requirements of the federal Health Insurance Portability and Accountability Act (HIPAA) and related regulations.

~~(B) An electronic signature that meets the requirements of 105 CMR 721.031 shall have the full force and effect of a handwritten signature on a paper-based written prescription.~~

~~(C) A paper-based written prescription must be written and signed by the practitioner in accordance with M.G.L. c. 94C, § 23 and 105 CMR 721.00.~~

721.040: Invalid Prescriptions

(A) A prescription in a format that does not conform to 105 CMR 721.000 is invalid and shall not be filled.

(B) A prescription that does not meet the security requirements of 105 CMR 721.000 is invalid and shall not be filled.

**(C) An electronic prescription transmitted through means other than electronic transmission is invalid.**

721.050: Prescribing More than One Drug Product

Practitioners who wish to prescribe more than one drug product, with the same or different dispensing instructions, shall place each prescription on a separate prescription form or record. More than one drug product may be prescribed in the hospital setting on a single form or record provided, however, that the prescription provides clear directions for use and interchange of each drug product.

**721.055: Partial Fill Prescriptions**

Comment [A16]: This section is added to address M.G.L. c. 94C, § 19(d¾), as inserted by chapter 52 of the acts of 2016 and amended by chapter 208 of the acts of 2018.

**(A) A pharmacist filling a prescription for a schedule II controlled substance shall, if requested by the patient, dispense the prescribed controlled substance in a lesser quantity than indicated on the prescription, pursuant to M.G.L. c. 94C, § 18(d¾). If the prescription was issued by a prescriber from a location other than the Commonwealth of Massachusetts, as indicated by the address of the prescriber on the prescription, the prescription must be presented for initial partial fill not later than five calendar days after the prescription issue date.**

**(B) Where a prescription has been partially filled in accordance with 105 CMR 721.055(A), the remaining portion of the prescription may be filled upon patient request in accordance with federal law; provided, however, that:**

**(1) only the same pharmacy that originally dispensed the lesser quantity shall dispense the remaining portion; and**

**(2) the remaining portion of the prescription is filled not later than 30 days after the prescription issue date.**

**(C) Upon dispensing a partial fill of a prescription under 105 CMR 721.055(A), or dispensing the remaining portion of the prescription under 105 CMR 721.055(B), the pharmacist or the pharmacist's designee shall make a notation in the patient's record maintained by the pharmacy, which shall be accessible to the prescribing practitioner by request, indicating that the prescription was partially filled and the quantity dispensed.**

721.060: **ePrescribing and** Emergency Situations ~~in Which Controlled Substances in Schedule II May Be Dispensed upon Orally or Electronically Transmitted Prescription~~

Comment [A17]: Section amended to include requirements and process when an emergency situation prevents ePrescribing. Paragraph (C) and (D) - special procedures for emergency prescribing of Schedule II medications, moved to new section, 721.065.

(A) **For the purposes of 105 CMR 721.000, the term "**~~E~~emergency situations**" means:** ~~, for the purpose of permitting the dispensing of any controlled substance in Schedule II upon orally or electronically transmitted prescription, means those situations in which the practitioner who intends to prescribe a controlled substance in Schedule II determines:~~

**(1) an emergency defined in Department guidance by the Commissioner acting pursuant to M.G.L. c. 94C, § 17; or** ~~the immediate administration of the controlled substance is necessary for the proper treatment of the intended ultimate user;~~

**(2) situations in which the prescribing practitioner intends to prescribe a controlled substance, the immediate administration of which is necessary for the proper treatment of the intended ultimate user;** ~~no appropriate alternative treatment is available, including administration of a controlled substance which is not in Schedule II;~~ and

~~(3)~~ **a.** it is not reasonably possible for the prescribing practitioner to ~~provide a written~~ **generate or transmit an electronic** prescription to be presented to the person dispensing the controlled substance prior to the dispensing; **or**

**b. the prescribing practitioner determines that the electronic prescription requirement would result in a delay that would adversely impact the patient's medical condition.**

Comment [A18]: Added pursuant to M.G.L. c. 94C, § 23(h)(iv), as amended by chapter 208 of the acts of 2018.

(B) In case of an emergency situation as defined in 105 CMR 721.060(A), **the requirements of 105 CMR 721.000 to use an electronic prescribing system to generate, transmit and receive a prescription are waived. In these situations, written and oral prescriptions may be issued and must comply with all other prescription requirements.** ~~a pharmacist may dispense a controlled substance in Schedule II upon receiving the orally or electronically transmitted authorization of a prescribing practitioner, provided:~~

~~(1) the quantity prescribed and dispensed is limited to the amount adequate to treat the patient during the emergency period;~~

~~(2) the prescription contains all information required by M.G.L. c. 94C, § 20(a) except for the actual signature of the prescribing practitioner, and in the case of an oral prescription, or prescription transmitted electronically by computer modem or other similar electronic device, the prescription is immediately reduced to writing by the dispensing pharmacist; and~~

~~(3) the dispensing pharmacist makes a reasonable good faith effort to determine that the orally or electronically transmitted authorization was issued by an authorized practitioner, which effort may include a callback to the prescribing practitioner or other good faith efforts to ensure the prescribing practitioner's identity.~~

~~(C) Within 72 hours after authorizing an emergency orally or electronically transmitted prescription, the prescribing practitioner shall cause a written prescription for the emergency quantity prescribed to be delivered to the pharmacy which must have written on its face "Authorization for Emergency Dispensing" and shall comply with federal and state law. The written prescription may be delivered to the pharmacist in person or by mail, but if delivered by mail, it must be postmarked within the 72 hour period.~~

~~(D) Upon receipt of the written prescription, the dispensing pharmacist shall attach the prescription to the orally or electronically transmitted emergency prescription which had earlier been reduced to writing. The pharmacist shall notify the nearest office of the Drug Enforcement Administration, U.S. Department of Justice, and the Commissioner of Public Health, Massachusetts Department of Public Health if the prescribing individual practitioner fails to deliver a written prescription to the pharmacist within 72 hours.~~

**721.065: Special Procedures for Emergency Prescribing and Dispensing of Schedule II Controlled Substances**

Comment [A19]: Reformatted to make 721.060(C) and (D) a new section, 721.065, to distinguish emergencies under M.G.L. c. 94C, § 17 from Schedule II emergencies.

(A) In case of an emergency situation as defined in 105 CMR 721.060(A), a pharmacist may dispense a controlled substance in schedule II upon receiving the orally transmitted authorization of a prescribing practitioner, provided:

(1) the quantity prescribed and dispensed is limited to the amount adequate to treat the patient during the emergency period;

(2) the prescription contains all information required by M.G.L. c. 94C, § 20(a) except for the actual signature of the prescribing practitioner, and the prescription is immediately entered into a compliant electronic pharmacy system or otherwise reduced to writing by the dispensing pharmacist;

(3) the dispensing pharmacist makes a reasonable good faith effort to determine that the orally transmitted authorization was issued by a prescribing practitioner, which effort may include a telephone call to the prescribing practitioner or other good faith efforts to ensure the prescribing practitioner's identity; and

(4) after authorizing an emergency orally transmitted prescription, the prescribing practitioner shall cause an electronic prescription for the emergency quantity prescribed to be transmitted to the pharmacy which must include the notation "Authorization for Emergency Dispensing" and shall comply with federal and state law. The electronic prescription must be transmitted within two business days. If the prescriber qualifies under 105 CMR 721.070, a written prescription must be transmitted in accordance with 105 CMR 721.020(F).

(B) Upon receipt of the prescription issued under 105 CMR 721.065(A)(4), the dispensing pharmacist shall attach the prescription to the orally transmitted emergency prescription which had earlier been reduced to writing. The pharmacist shall notify the nearest office of the Drug Enforcement Administration, U.S. Department of Justice, and the Commissioner if the prescribing practitioner fails to deliver a prescription to the pharmacist in accordance with 105 CMR 721.065(A)(4).

**721.070: ePrescribing Exceptions**

(A) The following prescriptions shall not be required to be issued as electronic prescriptions, and may be issued as written or oral prescriptions, provided, however, that a practitioner issuing an oral prescription must comply with 105 CMR 721.070(B):

Comment [A20]: Reference to follow-up written prescription requirements

(1) prescriptions issued by veterinarians;

Comment [A21]: Exception included in M.G.L. c. 94C, § 23(h)(i), as inserted by chapter 208 of the acts of 2018.

(2) prescriptions issued or dispensed in circumstances where electronic prescribing is not available due to temporary technological or electrical failure;

Comment [A22]: Exception included in M.G.L. c. 94C, § 23(h)(ii), as inserted by chapter 208 of the acts of 2018.

(3) prescriptions issued by practitioners who have applied for and received a waiver pursuant to 105 CMR 721.075;

Comment [A23]: Exception included in M.G.L. c. 94C, § 23(h)(iii), as inserted by chapter 208 of the acts of 2018.

(4) prescriptions issued or dispensed in emergency situations pursuant to 105 CMR 721.060;

Comment [A24]: Exception included in M.G.L. c. 94C, § 23(h)(iv), as inserted by chapter 208 of the acts of 2018.

(5) prescriptions that cannot be issued electronically under federal or state law or regulations;

Comment [A25]: Exception included in M.G.L. c. 94C, § 23(h)(v), as inserted by chapter 208 of the acts of 2018.

(6) prescriptions issued outside the jurisdiction of the Commonwealth of Massachusetts;

Comment [A26]: Exception included in M.G.L. c. 94C, § 23(h)(vi); includes out-of-state, as well as Federally operated Veterans' Administration

(7) prescriptions issued pursuant to M.G.L. c. 111, § 121B for expedited partner therapy for treatment of chlamydia, which are intended for dispensing to the patient's partner;

Comment [A27]: ADDED Exception needed to prevent ePrescribing from compromising privacy and defeating the purpose of law.

(8) prescriptions for compounded drug preparations, subject to standards outlined in Department guidance;

Comment [A28]: ADDED Exception is necessary to ensure issuing and dispensing of tailored prescriptions remains possible.

(9) prescriptions issued by prescribers who hold a Massachusetts Controlled Substance Registration that authorizes schedule VI prescribing only; and

Comment [A29]: ADDED Exception allows prescribers of only non-federally controlled substances to utilize systems that meet the security requirements of 721.030.

(10) prescriptions for durable medical equipment, as defined in 42 U.S.C. § 1395x(n).

Comment [A30]: ADDED Exception is necessary to ensure patient access to Medicaid and other insurance coverage for needed in-home devices.

(B) A practitioner issuing an oral prescription for a controlled substance, in accordance with 105 CMR 721.070(A), shall, within a period of not more than seven business days, or such shorter period that is required by federal law, cause a written prescription for the prescribed controlled substance to be delivered to the dispensing pharmacy. .The written prescription may be delivered to the pharmacy in person or by mail, but shall be postmarked within seven business days or such shorter period that is required by federal law. The practitioner shall indicate on the written prescription that such prescription is being issued to document an oral prescription.

Comment [A31]: Required by M.G.L. c. 94C, § 20(C).

721.075: Time Limited Waivers of ePrescribing Requirements

Comment [A32]: This section outlines requirements and process for time-limited waiver, as required by M.G.L. c. 94C, § 23(h)(iii), as inserted by chapter 208 of the acts of 2018.

(A) The Commissioner may issue a time limited waiver to a health care facility or a prescriber of one or more of the requirements imposed through 105 CMR 721.000 upon a finding that:

(1) compliance would impose a demonstrable economic hardship on the applicant, or the applicant is impacted by technical limitations that are not reasonably within the applicant's control; and

(2) the applicant's temporary non-compliance does not jeopardize the health or safety of individuals or the public; and

(3) the applicant has instituted compensating measures that are acceptable to the Commissioner.

(B) The waiver applicant must provide the Commissioner with written documentation supporting its request for a waiver.

REGULATORY AUTHORITY

105 CMR 721.000: M.G.L. c. 30A, § 2; c. 94C, §§ 6, ~~c. 94C,~~ §17, 18, 20 and 23; c. 111, § 3; and c. 112, § 12D.